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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/064,682	04/22/1998	JACOB STEN PETERSEN	273802002200	6434

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[REDACTED] EXAMINER

SWARTZ, RODNEY P

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645  
DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/064,682	PETERSEN, JACOB STEN
	Examiner	Art Unit
	Rodney P. Swartz, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 30October2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-3 and 5-26 is/are pending in the application.

4a) Of the above claim(s) 21-26 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3 and 5-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-3,5-26 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2April2001 has been entered.

Claim 1, 12, 15, 19, and 20 have been amended.

2. Claims 1-3 and 5-26 are pending. Clams 21-26 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

3. Currently, claims 1-3 and 5-20 are under consideration.

### **Rejections Maintained**

4. The rejection of claims 1-3 and 5-20 under 35 U.S.C. 103(a) as being unpatentable over JP3109328 in view of Elson (*Current Topics in Microbiology*, 146:29-33, 1989) is maintained.

Applicants argue that JP3109328 concerns induction of tolerance by administering CTB alone, not administered as an effective combination with a substance normally resulting in an immune response. The instant claims are drawn to a combination of CTB and antigen, while JP3109328 administers CTB on or before the administration of the antigen, in order to generally suppress the immune system from rejecting the graft.

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The examiner has considered applicants' argument, but does not find it persuasive because the instant specification does not teach "specific" tolerance to one antigen as there are no simultaneous testing of other control antigens which would show that the induction of tolerance in the recipients was "specific" and was not a general tolerance induction. Likewise, the instant claims are drawn to a composition wherein the CTB and antigen are "in an unconjugated form". In addition, the instant specification does not teach that the CTB and antigen are required to be administered simultaneously in order to be effective tolerance induction agents. Therefore, JP3109328, by administering CTB and antigen (cells) in an unconjugated form does meet the scope of the instant claims.

Applicants argue that Elson does not disclose specific sustained immunological tolerance to a target antigen, but concerns the field of adjuvants, especially oral immunization with CT and CTB, and therefore, teaches away from the present invention which, in contrast, teaches the specific tolerance of a target antigen by suppression of the immune response to said antigen. Elson has been utilized to show that which it is very important for CTB to be administered by the same route and even at the same time as the antigen, and that when CTB is administered orally (i.e., mucosally) does not stimulate antibody response to the antigen.

Thus, because JP3109328 teaches that administration of CTB and antigen results in tolerance, and Elson teaches that oral administration would not stimulate antibody response to an antigen, it would have been obvious to administration of CTB and antigen by oral route to induce tolerance to the antigen.

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### Conclusion

5. Claims 1-3 and 5-20 are rejected.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

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January 13, 2003